JUN 2 7 2005



# 510(k) Summary, K042630

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| Applicant | Skincare Technology Inc.<br>119 W. Hubbard St.<br>Suite 300<br>Chicago, IL 60610 |
| Date | June 8, 2005 |
| Device Name | RevLight® Skincare System |
| Common Name | LED phototherapy |
| Classification name | Laser Instrument, Surgical Powered<br>Procode: GEX |
| Summary of Substantial Equivalence | RevLight® is substantially equivalent in respect to the intended use, design and method of operation to numerous cleared devices, including:<br>Product /510(k)<br>LED Systems<br>Super Nova/Acubeam (K001179)<br>OmniLux Blue (K030883)<br>Revive (OmniLux Red) (K030426)<br>ClearLight (K013623)<br>Aurora SR (K022266;K033946(supp))<br>Lovely I (K033946)<br>Soundskin Phototherapy System (K040103)<br>Massagers<br>Model HM-45 (K9354597) |
| Device Description | RevLight is a device that utilizes Light Emitting Diodes to provide LED light to the body. The base unit contains the power supplies and the control unit. Attachable to the base unit are three sets of Pulsators that deliver the light to the skin as they are moved over the skin surface. The output of the Pulsators ranges from 420-940nm. |
| Intended Use and Indications | RevLight is intended for use to provide LED light to the body, and with the large pulsators, facial massage. Depending on the wavelength(s) of light delivered by the detachable Pulsators that are connected to the base unit, RevLight is:<br>1. generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris (Blue Pulsators); and<br>2. generally indicated to provide topical heating to promote increased blood flow, relaxation of muscle and relief of pain (Amber/Red Pulsators). |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 2005

Skincare Technologies Incorporated
C/o Richard O. Wood
Bell, Boyd & Lloyd, LLC
70 West Madison Street, Suite 3300
Chicago, Illinois 60602-4207

Re: K042630
Trade/Device Name: RevLight® Skin Care System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: May 12, 2005
Received: May 13, 2005

Dear Mr. Wood:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

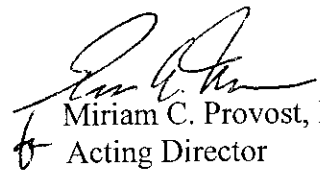
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number: _____**K042630**_____

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| Device Name: | RevLight® Skin Care System |
| Indications for Use (Large and Small Pulsators) | RevLight is intended for use to provide LED light to the body. |
| Indications for Use (Large Pulsators) | Facial massage. |
| Blue Pulsators | Used with the RevLight, are generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris. |
| Amber Pulsators | Used with the RevLight, are generally indicated to provide topical heating to promote increased blood flow, for temporary relaxation of muscle and relief of pain. |
| Red Pulsators | Used with the RevLight, are generally indicated to provide topical heating to promote increased blood flow, for temporary relaxation of muscle and relief of pain. |

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K042630